



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-1252]

Panray Corp. Sub Ormont Drug and Chemical Co., Inc., et al.; Withdrawal of Approval of Three New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of three new drug applications (NDAs) from multiple holders of those NDAs. The basis for the withdrawal is that these NDA holders have repeatedly failed to file required annual reports for the identified NDAs.

DATES: Approval is withdrawn as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993-0002, 301-796-3137, Kimberly.Lehrfeld@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The holder of an approved application to market a new drug for human use is required to submit annual reports to FDA concerning its approved application in accordance with § 314.81 (21 CFR 314.81).

In the *Federal Register* of December 27, 2021 (86 FR 73296), FDA published a notice offering an opportunity for a hearing (NOOH) on a proposal to withdraw approval of three NDAs because the holders of those NDAs had repeatedly failed to submit the required annual reports for those NDAs. The holders of those NDAs did not respond to the NOOH. Failure to file a written notice of participation and request for hearing as required by § 314.200 (21 CFR 314.200) constitutes an election by those holders of the NDAs not to make use of the opportunity

for a hearing concerning the proposal to withdraw approval of their NDAs and a waiver of any contentions concerning the legal status of the drug products. Therefore, FDA is withdrawing approval of the three applications listed in table 1 of this document.

Table 1.--Approved NDAs for Which Required Reports Have Not Been Submitted

Application No.	Drug	NDA Holder
NDA 008284	Cortisone Acetate Tablets, 5 milligrams (mg) and 25 mg	Panray Corp. Sub Ormont Drug and Chemical Co., Inc., 520 South Dean St., Englewood, NJ 07631
NDA 009659	Hydrocortisone Tablets, 10 mg and 20 mg	Do.
NDA 019503	Triamcinolone Acetonide Suspension, 3 mg/milliliters (mL)	Parnell Pharmaceuticals Inc., 111 Francisco Blvd., San Rafael, CA 94901

FDA finds that the holders of the NDAs listed in table 1 have repeatedly failed to submit reports required by § 314.81. In addition, under § 314.200, FDA finds that the holders of the NDAs have waived any contentions concerning the legal status of the drug products. Therefore, under these findings, approval of the NDAs listed in table 1 and all amendments and supplements thereto is hereby withdrawn as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

Dated: July 14, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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